



ZFW

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number 10/568,649

Filing Date February 16, 2006

First Named Inventor Georgio Terenghi

Art Unit Unassigned

Examiner Name Unassigned

Attorney Docket Number TEPH 109

**ENCLOSURES (Check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	Twenty-Six (26) Pages PTO-Form 1449; Two Hundred Twenty Six (226) References; and Return Receipt Postcard
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Pabst Patent Group LLP		
Signature			
Printed name	Patrea L. Pabst		
Date	August 30, 2006	Reg. No.	31,284

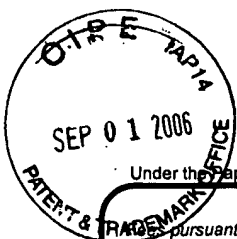
**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name	Carla Stone	Date	August 30, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

TEPH 109 077930/00023



PTO/SB/17 (01-06)

Approved for use through 07/31/2006. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL**  
**For FY 2006**☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0.00

**Complete if Known**

Application Number	10/568,649
Filing Date	February 16, 2006
First Named Inventor	Georgio Terenghi
Examiner Name	Unassigned
Art Unit	Unassigned
Attorney Docket No.	TEPH 109

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 50-3129 Deposit Account Name: Pabst Patent Group LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**FEE CALCULATION** (All the fees below are due upon filing or may be subject to a surcharge.)**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 20 or HP = _____ x _____ = _____		
HP = highest number of total claims paid for, if greater than 20.		
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 3 or HP = _____ x _____ = _____		
HP = highest number of independent claims paid for, if greater than 3.		

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fees Paid (\$)
- 100 = _____	/ 50 = _____	(round up to a whole number) x _____		

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): \_\_\_\_\_

Fees Paid (\$)

**SUBMITTED BY**

Signature	Registration No. 31,284	Telephone 404-879-2151
Name (Print/Type) Patrea L. Pabst	(Attorney/Agent)	Date

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

TEPH 109 077930/00023



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Georgio Terenghi, Para-Naz Mohana, and David P. Martin

Serial No.: 10/568,649

Art Unit: Not Yet Assigned

Filed: February 16, 2006

Examiner: Not Yet Assigned

For: *POLYHYDROXYALKANOATE NERVE REGENERATION DEVICES*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including twenty-six (26) pages of Form PTO-1449, and copies of two hundred and twenty-six (226) documents cited therein.

Pursuant to the waiver in the notice entitled "Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications Filed After June 30, 2003" published on August 5, 2003 in 1273 OG 55, copies of cited U.S. Patents are not enclosed. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1329.

### U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,598,122	08-10-1971	Zaffaroni et al.	128/268
3,598,123	08-10-1971	Zaffaroni et al.	128/268
3,731,683	05-08-1973	Zaffaroni	128/268
3,797,494	03-19-1974	Zaffaroni	128/268
3,982,543	09-28-1976	Schmitt, et al.	128/335.5
4,031,894	06-28-1977	Urquhart et al.	128/268
4,201,211	05-06-1980	Chandrasekaran et al.	128/268
4,286,592	08-01-1981	Chandrasekaran	128/260
4,314,557	02-09-1982	Chandrasekaran	128/260
4,379,454	04-12-1983	Campbell et al.	604/897
4,435,180	03-06-1984	Leeper	604/896
4,559,222	12-17-1985	Enscore et al.	424/28
4,573,995	03-04-1986	Chen et al.	604/896
4,588,580	05-13-1986	Gale et al.	424/21
4,603,070	07-29-1986	Steel et al.	428/88
4,645,502	02-24-1987	Gale et al.	604/896
4,648,978	03-10-1987	Makinen, et al.	210/759
4,664,655	05-12-1987	Orentreich, et al.	604/232
4,704,282	11-03-1987	Campbell et al.	424/449
4,711,241	12-08-1987	Lehmann	128/335.5
4,758,234	07-19-1988	Orentreich, et al.	604/232
4,788,062	11-29-1988	Gale et al.	424/449
4,792,336	12-20-1988	Hlavacek, et al.	623/13
4,816,258	03-28-1989	Nedberge et al.	424/448
4,826,493	05-02-1989	Martini, et al.	604/327
4,849,226	07-18-1989	Gale	424/448
4,856,188	08-15-1989	Sibalis	29/877
4,880,592	11-14-1989	Martini, et al.	264/514
4,908,027	03-13-1990	Enscore et al.	604/890.1
4,910,145	03-20-1990	Holmes, et al.	435/259
4,938,763	07-03-1990	Dunn, et al.	604/891.1
4,943,435	07-24-1990	Baker et al.	424/448
5,002,067	03-26-1991	Berthelsen, et al.	607/120
5,032,638	07-16-1991	Wang, et al.	524/400
5,085,629	02-04-1992	Goldberg, et al.	604/8
5,124,371	06-23-1992	Tokiwa, et al.	523/124
5,128,144	07-07-1992	Korsatko-Wabnegg, et al.	424/464
5,204,382	04-20-1993	Wallace, et al.	523/115
5,236,431	08-17-1993	Gogolewski, et al.	606/72
5,245,023	09-14-1993	Peoples, et al.	536/023.2

U.S.S.N.: 10/568,649  
 Filed: February 16, 2006  
 INFORMATION DISCLOSURE STATEMENT

5,250,430	10-05-1993	Peoples, et al.	435/232
5,271,961	12-21-1993	Mathiowitz, et al.	427/213.31
5,278,201	01-11-1994	Dunn, et al.	523/113
5,278,202	01-11-1994	Dunn, et al.	523/113
5,278,256	01-11-1994	Bellis	525/450
5,292,860	03-08-1994	Shiotani, et al.	528/361
5,306,286	04-26-1994	Stack, et al.	606/198
5,334,698	08-02-1994	Witholt, et al.	528/354
5,468,253	11-21-1995	Bezwada, et al.	606/230
5,480,394	01-02-1996	Ishikawa	604/327
5,480,794	01-02-1996	Peoples, et al.	435/23.2
5,489,470	02-06-1996	Noda	428/286
5,502,116	03-26-1996	Noda	525/415
5,502,158	03-26-1996	Sinclair et al.	528/354
5,512,669	04-30-1996	Peoples, et al.	536/23.2
5,516,565	05-14-1996	Matsumoto	428/35.7
5,534,432	07-09-1996	Peoples, et al.	435/240.4
5,536,564	07-16-1996	Noda	428/280
5,550,173	08-27-1996	Hammond, et al.	523/122
5,551,954	09-03-1996	Buscemi, et al.	623/1
5,563,239	10-08-1996	Hubbs, et al.	528/361
5,614,576	03-25-1997	Rutherford et al.	524/270
5,629,077	05-13-1997	Turnlund, et al.	442/38
5,625,030	05-29-1997	Williams et al.	528/361
5,635,215	06-03-1997	Boschetti, et al.	424/501
5,646,217	07-08-1997	Hammond	525/450
5,648,100	07-15-1997	Boschetti, et al.	424/501
5,670,161	09-23-1997	Healy, et al.	424/426
5,703,160	12-30-1997	Dehennua et al.	525/54.24
5,705,187	01-06-1998	Unger	424/450
5,709,854	01-20-1998	Griffiths-Cima, et al.	424/93.7
5,711,933	01-27-1998	Bichon, et al.	424/9.52
5,728,752	03-17-1998	Scopelianos, et al.	523/113
5,753,364	05-19-1998	Rutherford et al.	428/355
5,753,708	05-19-1998	Koehler et al.	514/629
5,811,272	09-22-1998	Snell, et al.	435/135
5,814,071	09-29-1998	McDevitt, et al.	606/232
5,814,599	09-29-1998	Mitragotri et al.	514/3
5,824,333	10-20-1998	Scopelianos, et al.	424/423
5,824,751	10-20-1998	Hori et al.	525/450
5,834,582	11-10-1998	Sinclair et al.	528/354
5,840,331	11-28-1998	Van Cauter, et al.	424/464
5,842,477	12-01-1998	Naughton, et al.	128/898

5,855,619	01-05-1999	Caplan, et al.	623/11
5,876,452	03-02-1999	Athanasίου, et al.	623/16
5,876,455	03-02-1999	Harwin	623/16
5,879,322	03-09-1999	Lattin et al.	604/20
5,919,478	07-06-1999	Landrau et al.	424/449
5,935,506	08-10-1999	Schmitz, et al.	264/400
5,990,162	11-23-1999	Scharf	514/533
5,994,478	11-30-1999	Asrar et al.	525/437
6,056,970	05-02-2000	Greenawalt, et al.	424/426
6,119,567	09-19-2000	Schindler, et al.	83/171
6,214,387	04-10-2001	Berde, et al.	424/501
6,245,537	06-12-2001	Williams, et al.	435/135
6,316,262	11-13-2001	Huisman, et al.	435/490
6,323,010	11-27-2001	Skraly, et al.	435/135
6,454,811	09-24-2002	Sherwood, et al.	623/23.76
6,514,515	02-04-2003	Williams	424/424
6,548,569	04-15-2003	Williams, et al.	523/124
6,555,123	04-29-2003	Williams, et al.	424/423
6,600,010	07-29-2003	Mao, et al.	528/400
6,610,764	08-26-2003	Martin, et al.	523/124
6,623,749	09-23-2003	Williams, et al.	424/423
6,656,489	12-02-2003	Mahmood, et al.	424/426
6,680,046	01-20-2004	Boschetti	424/9.1

#### U.S. Patent Applications

<u>Number</u>	<u>Publication Date</u>	<u>Inventor</u>	<u>Class/Subclass</u>
2003/0211131	11-13-2003	Martin, et al.	424/426

#### Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
2,259,098	07-13-1999	Meiji Seika Kaisha and Taisei Corp	CA
2,307,637	05-14-1999	Childrens Medical Center Corporation	CA
2166354	05-08-1986	Imperial Chemical	GB
39 37 649	05-16-1991	Boehringer Ingelheim Forschungsgesellschaft	DE
0 258 781	03-09-1988	American Cyanamid Co.	EP
0 344 704	12-06-1989	CT Lab Farm SRL	EP
0 349 505	03-01-1990	Astra Meditec AB	EP
0 423 484	04-24-1991	btF Biotechnologische	EP

U.S.S.N.: 10/568,649  
 Filed: February 16, 2006  
 INFORMATION DISCLOSURE STATEMENT

0 429 403	05-29-1991	Sigma-Tau Industrie Farmaceutiche Riunite	EP
0 432 443	06-19-1991	Boehringer Ingelheim	EP
0 452 111	10-16-1991	Takeda Chemical Industries	EP
0 507 554	10-07-1992	Mitsui Toatsu Chemicals, Inc.	EP
0 601 885	06-15-1994	Takasago International Corp.	EP
0 628 586	12-14-1994	Terumo Kabushiki Kaisha	EP
0 754 467	01-22-1997	Astra Aktiebolag	EP
1130043	09-05-2001	Canon Kabushiki Kaisha	EP
4-326932	11-16-1992	Nippon Zeon KK	JP
5-023189	02-02-1993	Mitsubishi Kasei Corp.	JP
5-194141	11-19-1993	Mitsubishi Kasei Corp.	JP
7-275344	10-24-1995	Nippon Zeon KK	JP
WO 92/18164	10-29-1992	Delta Biotech. Ltd.	PCT
WO 93/20134	10-14-1993	Alza Corporation	PCT
WO 94/02184	02-03-1994	Medinvent	PCT
WO 94/06886	03-31-1994	Biopak Technology, Ltd.	PCT
WO 95/03356	02-02-1995	Mass. Inst. of Tech.	PCT
WO 95/20614	08-03-1995	The Procter & Gamble Co.	PCT
WO 95/20615	08-03-1995	The Procter & Gamble Co.	PCT
WO 95/20621	08-03-1995	The Procter & Gamble Co.	PCT
WO 95/23250	08-31-1995	The Procter & Gamble Co.	PCT
WO 95/33874	12-14-1995	Minnesota Mining and Manufacturing Company	PCT
WO 96/00263	01-04-1996	Stichting Onerzoek En Ontwikkleing Noord	PCT
WO 96/08535	03-21-1996	The Procter & Gamble Co.	PCT
WO 96/18420	06-20-1996	Bracco Research SA	PCT
WO 96/21427	07-18-1996	Atrix Laboratories, Inc.	PCT
WO 96/40304	12-19-1996	Reprogenesis, Inc.	PCT
WO 97/07153	02-27-1997	University of Massachusetts Medical Center	PCT
WO 97/15681	05-01-1997	Metabolix Inc	PCT
WO 97/30042	08-21-1997	Global Art Co. Ltd	PCT
WO 98/04292	02-05-1998	Acusphere, Inc.	PCT
WO 98/39453	09-11-1998	Monsanto Co.	PCT
WO 98/48028	10-29-1998	Monsanto Company	PCT
WO 98/51812	11-19-1998	Metabolix, Inc.	PCT
WO 99/11196	03-11-1999	Point Biomedical Corp.	PCT
WO 99/14313	03-25-1999	Metabolix Inc	PCT
WO 99/32536	07-01-1999	Metabolix, Inc.	PCT
WO 99/35192	07-15-1999	Metabolix Inc.	PCT
WO 00/51662	09-08-2000	Tepha, Inc.	PCT

WO 00/56376	09-28-2000	Metabolix, Inc.	PCT
WO 01/15671	03-08-2001	Tepha, Inc.,	PCT
WO 01/19361	03-22-2001	Tepha, Inc.	PCT
WO 04/101002	11-25-2004	Tepha, Inc.	PCT

### Publications

ABATE, et al., "Separation and structural characterizations of cyclic and open chain oligomers produced in the partial pyrolysis of microbial poly(hydroxyutyrylates)", *Macromolecules*, 28(23):7911-1916 (1995).

ADDOLORATO, et al., "Maintaining abstinence from alcohol with gamma-hydroxybutyric acid", *The Lancet*, 351:38 (1998).

AGOSTINI, et al., "Synthesis and Characterization of Poly- $\beta$ -Hydroxybutyrate. I. Synthesis of Crystalline DL Poly- $\beta$ -Hydroxybutyrate from DL-  $\beta$ -Butyrolactone", *Polym. Sci. Part A-1*, 9:2775-87 (1971).

AKHTAR, "Physiomechanical Properties of bacterial P(HB-HV) Polyesters and Their Uses in drug Delivery", The British Library Document Supply Centre, UMI, (1990).

ANDERSON, et al., "Occurrence, Metabolism, metabolic Role, and Industrial Uses of bacterial Polyhydroxyalkanoates", *Microbiological Reviews*, 54(4):450-72 (1990).

ANDRIAMAMPANDRY, *et al.*, "Cloning of a rat brain succinic semialdehyde reductase involved in the synthesis of the neuromodulator  $\gamma$ -hydroxybutyrate", *Biochem. J.*, 334:43-50 (1998).

BAILEY, "Free radical ring-opening polymerization", *J. Polym. Preprints*, 25:210-11 (1984).

BAILEY, et al., "Synthesis of Poly- $\epsilon$ -caprolactone via a free radical mechanism. Free radical ring-opening polymerization of 2-methylene-1,3-dioxepane", *J. Polym. Sci. Polym. Chem.*, 20:3021-30 (1982).

BANDIERA, et al., "Effect of sodium sulfonate groups on the ionic conductivity of a copolyester of thiodipropionic acid", *Eur. Pol. J.*, 33:1679-1683 (1997).

BEHREND, "PHB as a bioresorbable material for intravascular stents", *American J. Cardiol.*, TCT Abstracts/Oral 4S:TCT-8 (Oct. 1998).

BERDE, et al., "Sustained release of dibucaine from a biodegradable polymer matrix: A potential method for prolooged neural blockade", Abstracts of Scientific Papers, 1990 Annual Meeting, Ameri. Soc. Anesthesiologists, 73(3A):A776, September, (1990).



BERGER, et al., "PHB recovery by hypochlorite digestion of non-PHB biomass", *Biotechnonology Techniques*, 3(4):227-232 (1989).

BOEREE, et al., "Development of a degradable composite for orthopaedic use: mechanical evaluation of an hydroxyapatite-polyhydroxybutyrate composite material", *Biomaterials*, 14(10):793-6 (1993).

BRANDL, et al., "*Pseudomonas oleovorans* as a source of poly(b-hydroxyalkanoates for potential applications as biodegradable polyesters", *Appl. Environ. Microbiol.*, 54:1977-1982 (1988).

BRAUNEGG, et al., "Polyhydroxyalkanoates, biopolyesters from renewable resources: physiological and engineering aspects", *J. Biotech.*, 65: 127-161 (1998).

BREUER, et al., "Tissue Engineering Lamb Heart Valve Leaflets", *Biotechnology & Bioengineering*, 50:562-67 (1996).

BRUHN and MÜLLER, "Preparation and characterization of spray-dried Poly(DL-Lactide) Micro Spheres", *Proceed. Intern. Symp. Control. Rel. Bioact. Mater.*, 18:668-69 (1991).

BYROM, "Miscellaneous Biomaterials" in Biomaterials (D. Byrom, ed.) pp. 333-59 (MacMillan Publishers, London 1991).

CAMPBELL & BAILEY, "Mechanical properties of suture materials *in vitro* and after *in vivo* implantation in horses", *Vet. Surg.*, 21(5):355-61 (1992).

CHU, et al., Wound Closure Biomaterials and Devices CRC Press:Boca Raton, 1996.

COLOMBO, et al., "Involvement of GABA(A) and GABA(B) receptors in the mediation of discriminative stimulus effects of gamma-hydroxybutyric acid", *Physiology & Behavior*, 64:293-302 (1998).

CONTI, et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems", *J. Microencapsulation* 9:153-166 (1992).

COOKSON, "It grows on trees", *Financial Times*, p. 6 (August 12, 1992).

CUEBAS, et al., "Mitochondrial metabolism of 3-mercaptopropionic acid. Chemical synthesis of 3-mercaptopropionyl coenzyme A and some of its S-acyl derivatives", *J. Biol. Chem.*, 260:7330-7336 (1985).

DAMIEN & PARSONS, "Bone graft and bone graft substitutes: a review of current technology and applications", *J. Appl. Biomater.*, 2(3):187-208 (1991).

DAYTON, *et al.*, "Use of an absorbable mesh to repair contaminated abdominal-wall defects", *Arch Surg.*, 121:954-960 (1986).

DE GROOT, "Meniscal tissue regeneration in porous 50/50 copoly(L-lactide/epsilon-caprolactone) implants", *Biomaterials*, 18(8):613-22 (1997).

DE KONING, *et al.*, "A biodegradable rubber by crosslinking poly(hydroxyalkanoate) from *Pseudomonas oleovorans*", *Polymer*, 35:2090-97 (1994)

DE SMET, *et al.*, "Characterization of intracellular inclusions formed by *Pseudomonas oleovorans* during growth on octane", *J. Bacteriol.*, 154:870-78 (1983).

DUBOIS, *et al.*, "Macromolecular Engineering of Polylactones and Polylactides. 12. Study of the Depolymerization Reactions of Poly (-caprolactone) with Functional Aluminum Alkoxide End Groups", *Macromolecules*, 26:4407-12 (1993).

DUVERNOY, *et al.*, "A biodegradable patch used as a pericardial substitute after cardiac surgery: 6- and 24-month evaluation with CT", *Thorac. Cardiovasc. Surg.*, 43(5):271-74 (1995).

Encyclopedic Handbook of Biomaterials and Bioengineering, Part A: Materials, Vol 1  
eds. Wise, *et al.*; Marcel Dekker, Inc., New York, 1995.

ENTHOLZNER, *et al.*, "EEG changes during sedation with gamma-hydroxybutyric acid", *Anaesthetist*, 44:345-350 (1995).

FRASER, *et al.*, "Controlled release of a GnRH agonist from a polyhydroxybutyric acid implant-reversible suppression of the menstrual cycle in the macaque", *Acta Endocrinol.*, 121:841-848 (1989).

FREED, *et al.*, "Biodegradable polymer scaffolds for tissue engineering ", *Biotechnology*, 12:689-693 (1994).

FÜCHTENBUSCH, *et al.*, "Biosynthesis of novel copolyesters containing 3-hydroxypivalic acid by *Rhodoccus ruber* NCIMB 40126 and related bacteria", *FEMS Microbiol. Lett.*, 159:85-92 (1998).

FUKUZAKI, *et al.*, "Direct copolymerization of L-lactic acid with  $\gamma$ -butyrolactone in the absence of catalysts", *Die Makromolekulare Chemie*, 190:1553-59 (1989).

GABBAY, *et al.*, "New outlook on pericardial substitution after open heart operations", *Ann. Thorac. Surg.*, 48(6):803-12 (1989).

GAGNON, *et al.*, "A thermoplastic elastomer produced by the bacterium *Pseudomonas oleovorans*", *Rubber World*, 207:32-38 (1992).

GAGNON, et al., "Chemical modification of bacterial elastomers: 1. Peroxide crosslinking", *Polymer*, 35:4358-67 (1994).

GAGNON, et al., "Chemical modification of bacterial elastomers: 2. Sulfur vulcanization", *Polymer*, 35:4368-75 (1994).

GERNGROSS and MARTIN, "Enzyme-catalyzed synthesis of poly[(R)-(-)-3-hydroxybutyrate]: formation of macroscopic granules in vitro", *Proc. Natl. Acad. Sci. USA*, 92:6279-83 (1995).

GERRA, et al., "Flumazenil effects on growth hormone response to gamma-hydroxybutyric acid", *International Clinical Psychopharmacology*, 9:211-215 (1994).

GRIEBEL, et al., "Metabolism of poly-beta-hydroxybutyrate. I. Purification, composition, and properties of native poly-beta-hydroxybutyrate granules from *Bacillus megaterium*", *Biochemistry*, 7:3676-3681 (1968).

GROSS, et al., "Polymerization of  $\beta$ -Monosubstituted- $\beta$ -propiolactones Using Trialkylaluminum-Water Catalytic Systems and Polymer Characterization", *Macromolecules*, 21:2657-68 (1988).

GUGALA, et al., "Regeneration of segmental diaphyseal defects in sheep tibiae using resorbable polymeric membranes: a preliminary study", *J. Orthop. Trauma*, 13(3):187-95 (1999).

GÜRSEL, et al., "In vivo application of biodegradable controlled antibiotic release systems for the treatment of implant-related osteomyelitis," *Biomaterials* 22: 73-80 (2001).

HADLOCK, et al., "Ocular cell monolayers cultured on biodegradable substrates", *Tissue Eng.*, 5(3):187-96 (1999).

HAZARI, et al., "A new resorbable wrap-around implant as an alternative nerve repair technique", *J. Hand Surgery*, 24(3): 291-295 (1999).

HAZARI, et al., "A resorbable nerve conduit as an alternative to nerve autograft in nerve gap repair", *Br J Plast Surg.*, 52(8):653-7 (1999).

HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of *Escherichia coli*.", *FEMS Microbiol. Lett.*, 153:411-18 (1997).

HEYDORN, et al., "A new look at pericardial substitutes", *J. Thorac. Cardiovasc. Surg.*, 94:291-96 (1987).

HOCKING & MARCHESSAULT, "Biopolyesters" in Chemistry and Technology of Biodegradable Polymers, (G.J.L. Griffin, ed.), pp. 48-96, Chapman and Hall: London, 1994.

HOCKING & MARCHESSAULT, "Syndiotactic poly[(R,S)- $\beta$ -hydroxybutyrate] isolated from methyaluminoxane-catalyzed polymerization", *Polym. Bull.*, 30:163-70 (1993).

HOLMES, "Biologically Produced (R)-3-hydroxyalkanoate Polymers and Copolymers", in Developments in Crystalline Polymers (Bassett, ed.), pp. 1-65, Elsevier: London, 1988.

HOLMES, et al., "Applications of PHB—a microbially produced biodegradable thermoplastic", *Phys Technol.*, 16:32-36 (1985).

HORI, et al., "Chemical synthesis of high molecular weight poly(3-hydroxybutyrate-co-4-hydroxybutyrate)", *Polymer*, 36:4703-05 (1996).

HORI, et al., "Ring-Opening Copolymerization of Optically Active  $\beta$ -Butyrolactone with Several Lactones Catalyzed by Distannoxane Complexes: Synthesis of New Biodegradable Polyesters", *Macromolecules*, 26:4388-90 (1993).

HORI, et al., "Ring-Opening Polymerization of Optically Active  $\beta$ -Butyrolactone Using Distannoxane Catalysts: Synthesis of High Molecular Weight Poly(3-hydroxybutyrate)", *Macromolecules*, 26:5533-34 (1993).

HOROWITZ, et al., "Novel Thermal Route to an Amorphous, Film-Forming Polymer Latex", *Macromolecules*, 32:3347-3352 (1999).

HORSCH, "Inheritance of Functional Foreign Genes in Plants" *Science*, 223: 496-498 (1984).

HUIJBERTS, et al., "Pseudomonas putida KT2442 cultivated on glucose accumulates poly(3-hydroxyalkanoates) consisting of saturated and unsaturated monomers", *Appl Environ Microbiol.*, 58(2):536-44 (1992).

HUTMACHER, et al., "A review of material properties of biodegradable and bioresorbable polymers and devices for GTR and GBR applications", *Int. J. Oral Maxillofac. Implants*, 11(5):667-78 (1996).

KAMEYAMA, et al., "Novel sequence-ordered polymers by transformation of polymer backbone: Quantitative and regioselective insertion of Thiranes into poly( S-aryl thioester)", *Macromol.*, 32:1407-1412 (1999).

KASSAB, et al., "Embolization with polyhydroxybutyrate (PHB) microspheres: In vivo studies", *J. Bioact. Compat. Polym.*, 14:291-303 (1999).

KAUFMAN and NELSON, "An overview of gamma-hydroxybutyrate catabolism: the role of the cytosolic NADP(+)-dependent oxidoreductase EC 1.1.1.19 and of a mitochondrial hydroxyacid-oxoacid transhydrogenase in the initial, rate-limiting step in this pathway", *Neurochemical Research*, 16:965-974 (1991)

KEELER, "Don't Let Food Go To Waste- Make Plastic Out of It", *R&D Magazine*, pp. 52-57 (1991).

KEELER, "Plastics Grown in Bacteria Inch Toward the Market", *R&D Magazine*, pp. 46-52 (1991).

KEMNITZER, et al., "Preparation of predominantly Syndiotactic Poly( $\beta$ -hydroxybutyrate) by the Tributyltin Methoxide Catalyzed Ring-Opening Polymerization of racemic  $\beta$ -Butyrolactone", *Macromolecules*, 26:1221-29 (1993).

KIM and MOONEY, "Engineering smooth muscle tissue with a predefined structure", *J. Biomed. Mat. Res.*, 41(2):322-332 (1998).

KISHIDA, et al., "Formulation-assisted biodegradable polymer matrices", *Chemical and Pharmaceutical Bulletin*, 37:1954-56 (1989).

KLEINSCHMIDT, et al., "Continuous sedation during spinal anaesthesia: gamma-hydroxybutyrate vs. propofol", *European Journal of Anaesthesiology*, 16:23-30 (1999).

KLEINSCHMIDT, et al., "Total intravenous anaesthesia using propofol, gamma-hydroxybutyrate or midazolam in combination with sufentanil for patients undergoing coronary artery bypass surgery", *European Journal of Anesthesiology*, 14:590-599 (1997).

KLINGE, et al., "Functional assessment and tissue response of short- and long-term absorbable surgical meshes", *Biomaterials*, 22:1415-1424 (2001).

KOOSHA, "Preparation and characterization of biodegradable polymeric drug carriers", Ph.D. Dissertation, 1989, Univ. Nottingham, UK., *Diss. Abstr. Int.*, B 51:1206 (1990).

KOOSHA, et al., "Polyhydroxybutyrate as a drug carrier", *Crit. Rev. Ther. Drug Carrier Syst.*, 6(2):117-30 (1989).

KORKUSUZ, et al., "In vivo response to biodegradable controlled antibiotic release systems," *J. Biomed. Mater. Res.* 55: 217-228 (2001).

KORSATKO, et al., "The influence of the molecular weight of poly-D(-)-3-hydroxybutyric acid on its use as a retard matrix for sustained drug release", *8<sup>th</sup> Europ. Congress of Biopharmaceutics and Pharmacokinetics*, 1:234-242 (1987).

KORTE and GELT, "Hochdruckreaktionen. II. Die Polymerisation Von  $\gamma$  butyrolacton und  $\gamma$ -valerolactam bei hohen drücken", *Polymer Lett.*, 4:685-89 (1966).

KUSAKA, et al., "Microbial synthesis and Physical Properties of ultra-high-molecular-weight poly[(R)-3-hydroxybutyrate]", *Pure Appl. Chem.*, A35:319-35 (1998).

LAFFERTY, et al., "Microbial Production of Poly-b-hydroxybutyric acid" in *Biotechnology* (H.J. Rehm and G. Reed, eds.), Verlagsgesellschaft, Weinheim, vol. 66, pp. 135-76 (1988).

LAMBA, et al., "Degradation of polyurethanes", in *Polyurethanes in Biomedical Applications* (CRC Press:Boca Raton, Florida, 1998).

LANZA, et al., *Principles of Tissue Engineering* (Academic Press:Austin, 1997).

LE BORGNE and SPASSKY, "Stereolective polymerization of  $\beta$ -butyrolactone", *Polymer*, 30:2312-19 (1989).

LEBEDEV and YEVSTROPOV, "Thermoplastic properties of polylactones", *Makromol. Chem.*, 185:1235-1253 (1984).

LEE, et al., "Copolymerization of  $\gamma$ -butyrolactone and  $\beta$ - butyrolactone", *Macromol. Chem. Phys.*, 198:1109-20 (1997).

LEMOIGNE and ROUKHELMAN, "Fermentation  $\beta$ -Hydroxybutyrique Caracterisation et Evolution Des Produits de Deshydratation et de Polymerisation de L'acide  $\beta$ -Dehydroxybutyrique", *Annales des fermentations*, 5:527-36 (1925).

LJUNGBERG, et al. "Neuronal survival using a resorbable synthetic conduit as an alternative to primary nerve repair", *Microsurgery*, 19(6):259-264 (1999).

LLOYD, et al., "Transformation of *Arabidopsis thaliana* with *Agrobacterium tumefaciens*", *Science*, 234: 464-66 (1986).

LÜTKE-EVERSLOH et al., "Identification of a new class of biopolymer: Bacterial synthesis of a sulfur-containing polymer with thioester linkages", *Microbiology*, 147(1): 11-19 (2001).

LÜTKE-EVERSLOH et al., "List of submitted abstracts", *The 8<sup>th</sup> International Symposium on Biological Polyesters*, (2000).

MADISON and HUISMAN, "Metabolic engineering of poly(3-hydroxyalkanoates): from DNA to plastic", *Microbiol. Molec. Biol. Rev.*, 63:21-53 (1999).

MALM, et al., "A new biodegradable patch for closure of atrial septal defect. An experimental study", *Scand. J. Thorac. Cardiovasc. Surg.*, 26(1):9-14 (1992).

MALM, et al., "Enlargement of the right ventricular outflow tract and the pulmonary artery with a new biodegradable patch in transannular position", *Eur. Surg. Res.*, 26(5):298-308 (1994).

MALM, et al., "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches. An experimental study", *J. Thorac. Cardiovasc. Surg.*, 104(3):600-07 (1992).

MARTIN and WILLIAMS, "Medical application of poly-4-hydroxybutyrate: A strong flexible absorbable biomaterial", *Biochem. Eng. J.*, 16:97-105 (2003).

MATHIOWITZ AND LANGER, "Polyanhydride microspheres as drug delivery systems" in *Microcapsules Nanopart. Med. Pharm.* (Donbrow, ed.), pp. 99-123 (CRC:Boca Raton, Florida, 1992).

MAYSINGER, "Microencapsulation and the Grafting of Genetically Transformed Cells as Therapeutic Strategies to rescue Degenerating Neurons of the CNS", *Reviews in the Neurosciences*, 6:15-33 (1995).

MCMILLIN, "Elastomers for Biomedical Applications", *Rubber Chem. Technol.*, 67:417-46 (1994).

MCWILLIAMS, "Plastics as High as an Elephant's Eye?" *Business Week*, pp. 110-11 (1991).

MODELLI, et al., "Kinetics of aerobic polymer degradation in soil by means of the ASTM D 5988-96 standard method", *J Environ Polym Degr*, 7:109-116 (1999).

MÜH, et al., "PHA synthase from chromatium vinosum: cysteine 149 is involved in covalent catalysis", *Bioche.*, 38:826-837 (1999).

MÜLLER, et al., "Poly(hydroxyalkanoates): A Fifth Class of Physiologically Important Organic Biopolymers", *Angew. Chem. Int. Ed. Engl.*, 32: 477-502 (1993).

NAKAMURA et al., "Biosynthesis and characteristics of bacterial poly(3-hydroxybutyrate-co-3-hydroxypropionate)", *Macromol. Rep.*, A28, 15-24 (1991).

NAKAMURA, et al., "Microbial synthesis and characterization of poly(3-hydroxybutyrate-co-4-hydroxybutyrate)", *Macromol.*, 25:4237-4241 (1992).

NELSON, et al., "The extraneural distribution of gamma-hydroxybutyrate", *J. Neurochem.*, 37:1345-1348 (1981).

NIKLASON, et al., "Functional arteries grown in vitro", *Science*, 284(5413):489-93 (1999).

NOBES, et al., "Polyhydroxyalkanoates: Materials for delivery systems", *Drug Del.*, 5:167-77 (1998).

OGAWA, et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Poly Lactic Acid or Copoly(Lactic/Glycolic) Acid", *Chem. Pharm. Bull.*, 36:1095-103 (1988).

OTERA, et al., "Distannoxane as reverse micelle-type catalyst: novel solvent effect on reaction rate of transesterification", *J. Org. Chem.*, 54:4013-14 (1989).

OTERA, et al., "Distannoxane-catalysed transesterification of 1,*n*-Dioldiacetates. Selective transformation of either of chemically equivalent functional groups", *J. Chem. Soc. Chem. Commun.*, 1742-43 (1991).

OTERA, et al., "Novel distannoxane-catalyzed transesterification and a new entry to  $\alpha,\beta$ -unsaturated carboxylic acids", *Tetrahedron Lett.*, 27:2383-86 (1986).

OTERA, et al., "Novel template effects of distannoxane catalysts in highly efficient transesterification and esterification", *J. Org. Chem.*, 56:5307-11 (1991).

PEDRÓS-ALIO *et al.*, "The influence of poly- $\beta$ -hydroxybutyrate accumulation on cell volume and buoyant density in *Alcaligenes eutrophus*", *Arch. Microbiol.* 143:178-184 (1985).

PEOPLES, et al., "Poly- $\beta$ -hydroxybutyrate Biosynthesis in *Alcaligenes eutrophus* H16", *J. Biol. Chem.*, 264(26):15293-97 (1989).

PEOPLES, et al., "Polyhydroxybutyrate (PHB): A Model System for Biopolymer Engineering: II", in Novel Biodegradable Microbial Polymers (Dawes, ed.) pp. 191-202, Kluwer Academic Publishers:Netherlands (1990).

PERRIN & ENGLISH, "Polycaprolactone", in Handbook of Biodegradable Polymers (Domb, et al., eds.) pp. 63-77 (Harwood, Amsterdam, 1997).

PINTO, "Hydrogen Peroxide as depyrogenation agent for medical devices components", *Revista De Saude Publica*, 29(1):75-79 (1995).

POIRIER, "Perspectives on the production of polyhydroxyalkanoates in plants", *FEMS Microbiology Reviews*, 103:237-46 (1992).



POIRIER, et al., "Progress Toward Biologically Produced Biodegradable thermoplastics", *Adv. Mater.*, 5(1):30-37 (1993).

POOL, "In Search of the Plastic Potato", *Science*, 245: 1187-89 (1989).

POUTON and AKHTAR, "Biosynthetic polyhydroxyalkanoates and their potential in drug delivery", *Adv. Drug Delivery Rev.*, 18:133-62 (1996).

REHM and STEINBÜCHEL, "Biochemical and genetic analysis of PHA synthases and other proteins required for PHA synthesis", *Int. J. Biol. Macromol.* 25:3-19 (1999).

RENSTAD, et al., "The influence of processing induced differences in molecular structure on the biological and non-biological degradation of poly (3-hydroxybutyrate-co-3-hydroxyvalerate), P(3-HB-co-3-HV)", *Polymer Degradation and Stability*, 63:201-211 (1999).

REYNOLDS, Martindale: The Extra Pharmacopeia, p. 1264, (Thirty First Edition, Royal Pharmaceutical Society, London, 1997).

RIVARD, et al., "Fibroblast seeding and culture in biodegradable porous substrates", *J. Appl. Biomater.*, 6(1):65-68 (1995).

ROPERO-MILLER & GOLDBERGER, "Recreational drugs. Current trends in the 90s", *Clinics in Laboratory Medicine*, 18:727-746 (1998).

SABBAGH, et al., "3-Mercaptopropionic acid, a potent inhibitor of fatty acid oxidation in rat heart mitochondria", *J. Biol. Chem.* 260:7337-7342 (1985).

SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in *Comamonas acidovorans*", *Int. J. Biol. Macromol.*, 16(2):99-104 (1994).

SCHARF, et al., "Pharmacokinetics of gammahydroxybutyrate (GHB) in narcoleptic patients", *Sleep* 21:507-514 (1998).

SCHLEGEL, et al., "Ein submersverfahren zur kultur wasserstoffoxydierender bakterien: Wachstumsphysiologische untersuchungen", *Arch. Mikrobiol.* 38:209-222 (1961).

SCHWARTZ and GOODMAN, Plastic Materials and Processes, (Van Nostrand Reinhold Company:New York, 1982).

SENDELBECK & GIRDIS, "Disposition of a 14C-labeled bioerodible polyorthoester and its hydrolysis products, 4-hydroxybutyrate and cis,trans-1,4-bis(hydroxymethyl)cyclohexane, in rats", *Drug Metabolism & Disposition* 13:291-295 (1985).

SHINOKA & MAYER, "New frontiers in tissue engineering: tissue engineered heart valves" in Synthetic Bioabsorbable Polymer Scaffolds (Atala & Mooney, eds.) pp. 187-198 Birkhäuser Boston, 1997.

SHINOKA, et al., "Creation of viable pulmonary artery autografts through tissue engineering", *J. Thorac. Cardiovasc. Surg.*, 115(3):536-46 (1998).

SHINOKA, et al., "Tissue engineering heart valves: valve leaflet replacement study in a lamb model" *Ann. Thorac. Surg.*, 60(Suppl 3):S513-16 (1995).

SIM, et al., "PHA synthase activity controls the molecular weight and polydispersity of polyhydroxybutyrate *in vivo*", *Nat. Biotechnol.*, 15(1):63-67 (1997).

SKREDE et al, "Thia fatty acids, metabolism and metabolic effects" in *Biochim Biophys Acta* 1344:115-31 (1997).

SNEAD, "The gamma-hydroxybutyrate model of absence seizures: correlation of regional brain levels of gamma-hydroxybutyric acid and gamma-butyrolactone with spike wave discharges", *Neuropharmacology* 30:161-167 (1991).

SONG, et al., "Production of poly(4-hydroxybutyric acid) by fed-batch cultures of recombinant strains of *Escherichia coli*", *Biotechnol. Lett.* 21:193-197 (1999).

SPEER and WARREN, "Arthroscopic shoulder stabilization. A role for biodegradable materials", *Clin. Orthop.*, (291):67-74 (1993).

STANTON and GAGNÉ, "The remarkable catalytic activity of alkali-metal alkoxide clusters in the ester interchange reaction", *J. Am. Chem. Soc.*, 119:5075-76 (1997).

STEINBÜCHEL and VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids", *FEMS Microbiol. Lett.*, 128:219-28 (1995).

STEINBÜCHEL and WIESE, "A *Pseudomonas* strain accumulating polyesters of 3-hydroxybutyric acid and medium-chain-length 3-hydroxyalkanoic acids", *Appl. Microbiol. Biotechnol.*, 37:691-97 (1992).

STEINBÜCHEL, "Polyhydroxyalkanoic Acids" in Biomaterials (Byrom, ed.), pp. 125-213 (MacMillan Publishers:London 1991).

STEINBÜCHEL, et al., "Molecular basis for biosynthesis and accumulation of polyhydroxyalkanoic acids in bacteria", *FEMS Microbiology Reviews*, 103: 217-30 (1992).

TAKAGI et al., "Biosynthesis of polyhydroxyalkanoate with a thiophenoxy side group obtained from *Pseudomonas putida*", *Macromolecules*, 32: 8315-8318 (1999).

TALJA, et al., "Bioabsorbable and biodegradable stents in urology", *J. Endourol.*, 11(6):391-97 (1997).

TANAHASHI and DOI, "Thermal Properties and Stereoregularity of Poly(3-hydroxybutyrate) Prepared from optically Active  $\beta$ -Butyrolactone with a Zinc-Based Catalyst", *Macromolecules*, 24:5732-33 (1991).

TANAKA, et al., "Clinical application of 4-hydroxybutyrate sodium and 4-butyrolactone in neuropsychiatric patients", *Folia Psychiatrica et Neurologica* 20:9-17 (1966).

TANGUAY, et al., "Current status of biodegradable stents", *Cardiol. Clin.*, 12(4):699-713 (1994).

Tepha announces submission of device master file to FDA (June 3, 2002). Retrieved 12-17-2004, from [http://www.pressrelease.be/script\\_UK/newsdetail.asp?ndays=m&ID=695](http://www.pressrelease.be/script_UK/newsdetail.asp?ndays=m&ID=695)

Tepha submits device master file to FDA- New Technology (July 2, 2002). Retrieved on 12-17-2004, from [http://www.findarticles.com/p/articles/mi\\_mOPC/is\\_7\\_26/ai\\_89018276](http://www.findarticles.com/p/articles/mi_mOPC/is_7_26/ai_89018276)

TSURUTA, et al., Biomedical Applications of Polymeric Materials (CRC Press, Boca Raton, Florida, 1993).

TUNNICLIFF, "Sites of action of gamma-hydroxybutyrate (GHB)--a neuroactive drug with abuse potential", *Clinical Toxicology*, 35:581-590 (1997).

TÜRESIN, et al., "Biodegradable polyhydroxyalkanoate implants for osteomyelitis therapy: *in vitro* antibiotic release," *J. Biomater. Sci. Polymer Edn.* 12: 195-207 (2001).

TURKE, "Absorbable Biomaterial is suited for diverse applications" (06-03-2002). Retrieved on 12-17-2004, from <http://www.devicelink.com/mpmn/archive/01/10/009.html>

UNVERDORBEN, et al., "Polyhydroxybutyrate (PHB) Biodegradable Stent-Experience in the Rabbit", *American J. Cardiol.*, TCT Abstracts/Oral, p.5S:TCT-11 (Oct. 1998).

VALENTIN, et al., "Identification of 4-hydroxyhexanoic acid as a new constituent of biosynthetic polyhydroxyalkanoic acids from bacteria", *Appl. Microbiol. Biotechnol.*, 40:710-16 (1994).

VALENTIN, et al., "Identification of 5-hydroxyhexanoic acid, 4-hydroxyheptanoic acid and 4-hydroxyoctanoic acid as new constituents of bacterial polyhydroxyalkanoic acids", *Appl. Microbiol. Biotechnol.*, 46:261-67 (1996).

VALENTIN, et al., "Production of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in recombinant *Escherichia coli* grown on glucose", *J. Biotechnol.*, 58:33-38 (1997).

VON SCHROEDER, et al., "The use of polylactic acid matrix and periosteal grafts for the reconstruction of rabbit knee articular defects", *J. Biomed. Mater. Res.*, 25(3):329-39 (1991).

WALLEN and ROHWEDDER, "Poly- $\beta$ -hydroxyalkanoate from Activated Sludge", *Environ. Sci. Technol.*, 8:576-79 (1974).

WIDMER and MIKOS, "Fabrication of biodegradable polymer scaffolds for tissue engineering" in Frontiers in Tissue Engineering (Patrick, et al., Eds.) Ch. II.5, pp.107-20 (Elsevier Science, New York, 1998).

WILLIAMS and PEOPLES, "Biodegradable plastics from plants", *Chemtech*, 26:38-44 (1996).

WILLIAMS, et al., "Application of PHAs in Medicine and Pharmacy", *Polyesters III*, 4:91-127 (2002).

WILLIAMS, et al., "Making plastics green", *Chem. Br.*, 33:29-32 (1997).

WILLIAMS, et al., "PHA applications: addressing the price performance issue. I. Tissue engineering", *Int. J. Biol. Macromol.*, 25(1-3): 111-121 (1999).

WODZINSKA, et al., "Polyhydroxybutyrate synthase: Evidence for covalent catalysis", *J. Am. Chem. Soc.* 118:6319-6320 (1996).

WONG and MOONEY, "Synthesis and properties of biodegradable polymers used as synthetic matrices for tissue engineering", in Synthetic Bio degradable Polymer Scaffolds (Atala, et al., eds.) pp. 51-82 (Birkhäuser: Boston, 1997).

WORSEY and WILLIAMS, "Metabolism of toluene and xylenes by *Pseudomonas putida* (arvilla) mt-2: evidence for a new function of the TOL plasmid" *J Bacteriol* 124:7-13 (1975).

XIE, et al., "Ring-opening Polymerization of  $\beta$ -butyrolactone by Thermophilic Lipases", *Macromolecules*, 30:6997-98 (1997).

YAGMURLU, et al., "Sulbactam-cefoperazone polyhydroxybutyrate-co-hydroxyvalerate (PHBV) local antibiotic delivery system: in vivo effectiveness and biocompatibility in the treatment of implant-related experimental osteomyelitis", *J Biomed Mater Res.*, 46(4):494-503 (1999).

YAMADA, et al., "Development of a dural substitute from synthetic bioabsorbable polymers", *J. Neurosurg.*, 86(6):1012-17 (1997).

U.S.S.N.: 10/568,649  
Filed: February 16, 2006  
INFORMATION DISCLOSURE STATEMENT

ZUND, et al., "The in vitro construction of a tissue engineered bioprosthetic heart valve",  
*Eur. J. Cardiothorac. Surg.*, 11(3):493-97 (1997).

U.S.S.N.: 10/568,649  
Filed: February 16, 2006  
INFORMATION DISCLOSURE STATEMENT

### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Dated: 8/30/2006

PABST PATENT GROUP LLP  
400 Colony Square, Suite 1200  
1201 Peachtree Street  
Atlanta, Georgia 30361  
(404) 879-2151 (Telephone)  
(404) 879-2160 (Fax)



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/568,649
Filing Date	February 16, 2006
First Named Inventor	Georgio Terenghi
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	TEPH 109

1 of 26

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		3,598,122		Zaffaroni et al.	08-10-1971	
		3,598,123		Zaffaroni et al.	08-10-1971	
		3,731,683		Zaffaroni	05-08-1973	
		3,797,494		Zaffaroni	03-19-1974	
		3,982,543		Schmitt, et al.	09-28-1976	
		4,031,894		Urquhart et al.	06-28-1977	
		4,201,211		Chandrasekaran et al.	05-06-1980	
		4,286,592		Chandrasekaran	08-01-1981	
		4,314,557		Chandrasekaran	02-09-1982	
		4,379,454		Campbell et al.	04-12-1983	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		CA	2,259,098		Meiji Seika Kaisha and Taisei Corp	07-13-1999		
		CA	2,307,637		Childrens Medical Center Corporation	05-14-1999		
		GB	2166354		Imperial Chemical	05-08-1986		
		DE	39 37 649		Boehringer Ingelheim Forschungsgesellschaft	05-16-1991		
		EP	0 258 781		American Cyanamid Co.	03-09-1988		
		EP	0 344 704		CT Lab Farm SRL	12-06-1989		

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/568,649	
			Filing Date	February 16, 2006	
			First Named Inventor	Georgio Terenghi	
			Group Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	26	Attorney Docket Number	TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		4,435,180		Leeper	03-06-1984	
		4,559,222		Enscore et al.	12-17-1985	
		4,573,995		Chen et al.	03-04-1986	
		4,588,580		Gale et al.	05-13-1986	
		4,603,070		Steel et al.	07-29-1986	
		4,645,502		Gale et al.	02-24-1987	
		4,648,978		Makinen, et al.	03-10-1987	
		4,664,655		Orentreich, et al.	05-12-1987	
		4,704,282		Campbell et al.	11-03-1987	
		4,711,241		Lehmann	12-08-1987	

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		EP	0 423 484		btF Biotechnologische	04-24-1991		
		EP	0 429 403		Sigma-Tau Industrie Farmaceutiche Riunite	05-29-1991		
		EP	0 432 443		Boehringer Ingelheim	06-19-1991		
		EP	0 452 111		Takeda Chemical Industries	10-16-1991		
		EP	0 507 554		Mitsui Toatsu Chemicals, Inc.	10-07-1992		
		EP	0 601 885		Takasago International Corp.	06-15-1994		

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/568,649	
			Filing Date	February 16, 2006	
			First Named Inventor	Georgio Terenghi	
			Group Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
Sheet	3	of	26	Attorney Docket Number	TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		4,758,234		Orentreich, et al.	07-19-1988	
		4,788,062		Gale et al.	11-29-1988	
		4,792,336		Hlavacek, et al.	12-20-1988	
		4,816,258		Nedberge et al.	03-28-1989	
		4,826,493		Martini, et al.	05-02-1989	
		4,849,226		Gale	07-18-1989	
		4,856,188		Sibalis	08-15-1989	
		4,880,592		Martini, et al	11-14-1989	
		4,908,027		Enscore et al.	03-13-1990	
		4,910,145		Holmes, et al.	03-20-1990	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		EP	0 628 586		Terumo Kabushiki Kaisha	12-14-1994		
		EP	0 754 467		Astra Aktiebolag	01-22-1997		
		EP	1130043		Canon Kabushiki Kaisha	09-05-2001		
		JP	4-326932		Nippon Zeon KK	11-16-1992		
		JP	5-023189		Mitsubishi Kasei Corp.	02-02-1993		
		JP	5-194141		Mitsubishi Kasei Corp.	11-19-1993		
		JP	7-275344		Nippon Zeon KK	10-24-1995		

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	4	of	26	Attorney Docket Number	TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		4,938,763		Dunn, et al.	07-03-1990	
		4,943,435		Baker et al.	07-24-1990	
		5,002,067		Berthelsen, et al.	03-26-1991	
		5,032,638		Wang, et al	07-16-1991	
		5,085,629		Goldberg, et al.	02-04-1992	
		5,124,371		Tokiwa, et al.	06-23-1992	
		5,128,144		Korsatko-Wabnegg, et al.	07-07-1992	
		5,204,382		Wallace, et al.	04-20-1993	
		5,236,431		Gogolewski, et al.	08-17-1993	
		5,245,023		Peoples, et al.	09-14-1993	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 92/18164		Delta Biotech. Ltd.	10-29-1992		
		PCT	WO 93/20134		Alza Corporation	10-14-1993		
		PCT	WO 94/02184		Medinvent	02-03-1994		
		PCT	WO 94/06886		Biopak Technology, Ltd.	03-31-1994		
		PCT	WO 95/03356		Mass. Inst. of Tech.	02-02-1995		
		PCT	WO 95/20614		The Procter & Gamble Co.	08-03-1995		
		PCT	WO 95/20615		The Procter & Gamble Co.	08-03-1995		

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number		10/568,649
				Filing Date		February 16, 2006
				First Named Inventor		Georgio Terenghi
				Group Art Unit		Not Yet Assigned
				Examiner Name		Not Yet Assigned
Sheet	5	of	26	Attorney Docket Number		TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,250,430		Peoples, et al.	10-05-1993	
		5,271,961		Mathiowitz, et al.	12-21-1993	
		5,278,201		Dunn, et al.	01-11-1994	
		5,278,202		Dunn, et al.	01-11-1994	
		5,278,256		Bellis	01-11-1994	
		5,292,860		Shiotani, et al.	03-08-1994	
		5,306,286		Stack, et al.	04-26-1994	
		5,334,698		Witholt, et al.	08-02-1994	
		5,468,253		Bezwada, et al.	11-21-1995	
		5,480,394		Ishikawa	01-02-1996	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		PCT	WO 95/20621		The Procter & Gamble Co.	08-03-1995	
		PCT	WO 95/23250		The Procter & Gamble Co.	08-31-1995	
		PCT	WO 95/33874		Minnesota Mining and Manufacturing Company	12-14-1995	
		PCT	WO 96/00263		Stichting Onerzoek En Ontwikkleing Noord	01-04-1996	
		PCT	WO 96/08535		The Procter & Gamble Co.	03-21-1996	
		PCT	WO 96/18420		Bracco Research SA	06-20-1996	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>			
			Application Number		10/568,649	
			Filing Date		February 16, 2006	
			First Named Inventor		Georgio Terenghi	
			Group Art Unit		Not Yet Assigned	
			Examiner Name		Not Yet Assigned	
Sheet	6	of	26	Attorney Docket Number		TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,480,794		Peoples, et al.	01-02-1996	
		5,489,470		Noda	02-06-1996	
		5,502,116		Noda	03-26-1996	
		5,502,158		Sinclair et al.	03-26-1996	
		5,512,669		Peoples, et al.	04-30-1996	
		5,516,565		Matsumoto	05-14-1996	
		5,534,432		Peoples, et al.	07-09-1996	
		5,536,564		Noda	07-16-1996	
		5,550,173		Hammond, et al.	08-27-1996	
		5,551,954		Buscemi, et al.	09-03-1996	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 96/21427		Atrix Laboratories, Inc.	07-18-1996		
		PCT	WO 96/40304		Reprogenesis, Inc.	12-19-1996		
		PCT	WO 97/07153		University of Massachusetts Medical Center	02-27-1997		
		PCT	WO 97/15681		Metabolix Inc	05-01-1997		
		PCT	WO 97/30042		Global Art Co. Ltd	08-21-1997		
		PCT	WO 98/04292		Acusphere, Inc.	02-05-1998		

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	7	of	26	Attorney Docket Number	TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,563,239		Hubbs, et al.	10-08-1996	
		5,614,576		Rutherford et al.	03-25-1997	
		5,629,077		Turnlund, et al.	05-13-1997	
		5,625,030		Williams et al.	05-29-1997	
		5,635,215		Boschetti, et al.	06-03-1997	
		5,646,217		Hammond	07-08-1997	
		5,648,100		Boschetti, et al.	07-15-1997	
		5,670,161		Healy, et al.	09-23-1997	
		5,703,160		Dehennua et al.	12-30-1997	
		5,705,187		Unger	01-06-1998	

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 98/39453		Monsanto Co.	09-11-1998		
		PCT	WO 98/48028		Monsanto Company	10-29-1998		
		PCT	WO 98/51812		Metabolix, Inc.	11-19-1998		
		PCT	WO 99/11196		Point Biomedical Corp.	03-11-1999		
		PCT	WO 99/14313		Metabolix Inc	03-25-1999		
		PCT	WO 99/32536		Metabolix, Inc.	07-01-1999		
		PCT	WO 99/35192		Metabolix Inc.	07-15-1999		

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/568,649	
			Filing Date	February 16, 2006	
			First Named Inventor	Georgio Terenghi	
			Group Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
Sheet	8	of	26	Attorney Docket Number	TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document. MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,709,854		Griffiths-Cima, et al.	01-20-1998	
		5,711,933		Bichon, et al.	01-27-1998	
		5,728,752		Scopelianos, et al.	03-17-1998	
		5,753,364		Rutherford et al.	05-19-1998	
		5,753,708		Koehler et al.	05-19-1998	
		5,811,272		Snell, et al.	09-22-1998	
		5,814,071		McDevitt, et al.	09-29-1998	
		5,814,599		Mitragotri et al.	09-29-1998	
		5,824,333		Scopelianos, et al.	10-20-1998	
		5,824,751		Hori et al.	10-20-1998	

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 00/51662		Tepha, Inc.	09-08-2000		
		PCT	WO 00/56376		Metabolix, Inc.	09-28-2000		
		PCT	WO 01/15671		Tepha, Inc.,	03-08-2001		
		PCT	WO 01/19361		Tepha, Inc.	03-22-2001		
		PCT	WO 04/101002		Tepha, Inc.	11-25-2004		

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	9	of	26	Attorney Docket Number	TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,834,582		Sinclair et al.	11-10-1998	
		5,840,331		Van Cauter, et al.	11-28-1998	
		5,842,477		Naughton, et al.	12-01-1998	
		5,855,619		Caplan, et al.	01-05-1999	
		5,876,452		Athanasious, et al.	03-02-1999	
		5,876,455		Harwin	03-02-1999	
		5,879,322		Lattin et al.	03-09-1999	
		5,919,478		Landrau et al.	07-06-1999	
		5,935,506		Schmitz, et al.	08-10-1999	
		5,990,162		Scharf	11-23-1999	
		5,994,478		Asrar et al.	11-30-1999	
		6,056,970		Greenawalt, et al.	05-02-2000	
		6,119,567		Schindler, et al.	09-19-2000	
		6,214,387		Berde, et al.	04-10-2001	
		6,245,537		Williams, et al.	06-12-2001	
		6,316,262		Huisman, et al.	11-13-2001	
		6,323,010		Skraly, et al.	11-27-2001	
		6,454,811		Sherwood, et al.	09-24-2002	
		6,514,515		Williams	02-04-2003	
		6,548,569		Williams, et al.	04-15-2003	
		6,555,123		Williams, et al.	04-29-2003	
		6,600,010		Mao, et al.	07-29-2003	
		6,610,764		Martin, et al.	08-26-2003	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(use as many sheets as necessary)</p>				Complete if Known	
				Application Number	10/568,649
				Filing Date	February 16, 2006
				First Named Inventor	Georgio Terenghi
				Group Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	10	of	26	Attorney Docket Number	TEPH 109

[illegible]

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>a</sup> Standard ST.37. <sup>b</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.  
<sup>c</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>d</sup> Applicant to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.**





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	11	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ABATE, et al., "Separation and structural characterizations of cyclic and open chain oligomers produced in the partial pyrolysis of microbial poly(hydroxybutyrate)", <i>Macromolecules</i> , 28(23):7911-1916 (1995).	
		ADDOLORATO, et al., "Maintaining abstinence from alcohol with gamma-hydroxybutyric acid", <i>The Lancet</i> , 351:38 (1998).	
		AGOSTINI, et al., "Synthesis and Characterization of Poly-β-Hydroxybutyrate. I. Synthesis of Crystalline DL Poly-β-Hydroxybutyrate from DL-β-Butyrolactone", <i>Polym. Sci. Part A-1</i> , 9:2775-87 (1971).	
		AKHTAR, "Physiomechanical Properties of bacterial P(HB-HV) Polyesters and Their Uses in drug Delivery", The British Library Document Supply Centre, UMI, (1990).	
		ANDERSON, et al., "Occurrence, Metabolism, metabolic Role, and Industrial Uses of bacterial Polyhydroxyalkanoates", <i>Microbiological Reviews</i> , 54(4):450-72 (1990).	
		ANDRIAMAMPANDRY, et al., "Cloning of a rat brain succinic semialdehyde reductase involved in the synthesis of the neuromodulator D-hydroxybutyrate", <i>Biochem. J.</i> , 334:43-50 (1998).	
		BAILEY, "Free radical ring-opening polymerization", <i>J. Polym. Preprints</i> , 25:210-11 (1984).	
		BAILEY, et al., "Synthesis of Poly-D-caprolactone via a free radical mechanism. Free radical ring-opening polymerization of 2-methylene-1,3-dioxepane", <i>J. Polym. Sci. Polym. Chem.</i> , 20:3021-30 (1982).	
		BANDIERA, et al., "Effect of sodium sulfonate groups on the ionic conductivity of a copolyester of thiodipropionic acid", <i>Eur. Pol. J.</i> , 33:1679-1683 (1997).	
		BEHREND, "PHB as a bioresorbable material for intravascular stents", <i>American J. Cardiol.</i> , TCT Abstracts/Oral 4S:TCT-8 (Oct. 1998).	
		BERDE, et al., "Sustained release of dibucaine from a biodegradable polymer matrix: A potential method for prolonged neural blockade", Abstracts of Scientific Papers, 1990 Annual Meeting, Ameri. Soc. Anesthesiologists, 73(3A):A776, September, (1990).	
Examiner's Signature		Date Considered	

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number		10/568,649
				Filing Date		February 16, 2006
				First Named Inventor		Georgio Terenghi
				Group Art Unit		Not Yet Assigned
				Examiner Name		Not Yet Assigned
Sheet	12	of	26	Attorney Docket Number		TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		BERGER, et al., "PHB recovery by hypochlorite digestion of non-PHB biomass", <i>Biotechnology Techniques</i> , 3(4):227-232 (1989).	
		BOEREE, et al., "Development of a degradable composite for orthopaedic use: mechanical evaluation of an hydroxyapatite-polyhydroxybutyrate composite material", <i>Biomaterials</i> , 14(10):793-6 (1993).	
		BRANDL, et al., " <i>Pseudomonas oleovorans</i> as a source of poly(b-hydroxyalkanoates for potential applications as biodegradable polyesters", <i>Appl. Environ. Microbiol.</i> , 54:1977-1982 (1988).	
		BRAUNEGG, et al., "Polyhydroxyalkanoates, biopolyesters from renewable resources: physiological and engineering aspects", <i>J. Biotech.</i> , 65: 127-161 (1998).	
		BREUER, et al., "Tissue Engineering Lamb Heart Valve Leaflets", <i>Biotechnology &amp; Bioengineering</i> , 50:562-67 (1996).	
		BRUHN and MÜLLER, "Preparation and characterization of spray-dried Poly(DL-Lactide) Micro Spheres", <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 18:668-69 (1991).	
		BYROM, "Miscellaneous Biomaterials" in <i>Biomaterials</i> (D. Byrom, ed.) pp. 333-59 (MacMillan Publishers, London 1991).	
		CAMPBELL & BAILEY, "Mechanical properties of suture materials <i>in vitro</i> and after <i>in vivo</i> implantation in horses", <i>Vet. Surg.</i> , 21(5):355-61 (1992).	
		CHU, et al., <i>Wound Closure Biomaterials and Devices</i> CRC Press:Boca Raton, 1996.	
		COLOMBO, et al., "Involvement of GABA(A) and GABA(B) receptors in the mediation of discriminative stimulus effects of gamma-hydroxybutyric acid", <i>Physiology &amp; Behavior</i> , 64:293-302 (1998).	
		CONTI, et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems", <i>J. Microencapsulation</i> 9:153-166 (1992).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>			
			Application Number		10/568,649	
			Filing Date		February 16, 2006	
			First Named Inventor		Georgio Terenghi	
			Group Art Unit		Not Yet Assigned	
			Examiner Name		Not Yet Assigned	
Sheet	13	of	26	Attorney Docket Number		TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		COOKSON, "It grows on trees", <i>Financial Times</i> , p. 6 (August 12, 1992).	
		CUEBAS, et al., "Mitochondrial metabolism of 3-mercaptopropionic acid. Chemical synthesis of 3-mercaptopropionyl coenzyme A and some of its S-acyl derivatives", <i>J. Biol. Chem.</i> , 260:7330-7336 (1985).	
		DAMIEN & PARSONS, "Bone graft and bone graft substitutes: a review of current technology and applications", <i>J. Appl. Biomater.</i> , 2(3):187-208 (1991).	
		DAYTON, et al., "Use of an absorbable mesh to repair contaminated abdominal-wall defects", <i>Arch Surg.</i> , 121:954-960 (1986).	
		DE GROOT, "Meniscal tissue regeneration in porous 50/50 copoly(L-lactide/epsilon-caprolactone) implants", <i>Biomaterials</i> , 18(8):613-22 (1997).	
		DE KONING, et al., "A biodegradable rubber by crosslinking poly(hydroxyalkanoate) from <i>Pseudomonas oleovorans</i> ", <i>Polymer</i> , 35:2090-97 (1994)	
		DE SMET, et al., "Characterization of intracellular inclusions formed by <i>Pseudomonas oleovorans</i> during growth on octane", <i>J. Bacteriol.</i> , 154:870-78 (1983).	
		DUBOIS, et al., "Macromolecular Engineering of Polylactones and Polylactides. 12. Study of the Depolymerization Reactions of Poly (-caprolactone) with Functional Aluminum Alkoxide End Groups", <i>Macromolecules</i> , 26:4407-12 (1993).	
		DUVERNOY, et al., "A biodegradable patch used as a pericardial substitute after cardiac surgery: 6- and 24-month evaluation with CT", <i>Thorac. Cardiovasc. Surg.</i> , 43(5):271-74 (1995).	
		Encyclopedic Handbook of Biomaterials and Bioengineering, Part A: Materials, Vol 1 eds. Wise, et al.; Marcel Dekker, Inc., New York, 1995.	
		ENTHOLZNER, et al., "EEG changes during sedation with gamma-hydroxybutyric acid", <i>Anaesthetist</i> , 44:345-350 (1995).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	14	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		FRASER, et al., "Controlled release of a GnRH agonist from a polyhydroxybutyric acid implant-reversible suppression of the menstrual cycle in the macaque", <i>Acta Endocrinol.</i> , 121:841-848 (1989).	
		FREED, et al., "Biodegradable polymer scaffolds for tissue engineering", <i>Biotechnology</i> , 12:689-693 (1994).	
		FÜCHTENBUSCH, et al., "Biosynthesis of novel copolyesters containing 3-hydroxypivalic acid by <i>Rhodococcus ruber</i> NCIMB 40126 and related bacteria", <i>FEMS Microbiol. Lett.</i> , 159:85-92 (1998).	
		FUKUZAKI, et al., "Direct copolymerization of L-lactic acid with $\gamma$ -butyrolactone in the absence of catalysts", <i>Die Makromolekulare Chemie</i> , 190:1553-59 (1989).	
		GABBAY, et al., "New outlook on pericardial substitution after open heart operations", <i>Ann. Thorac. Surg.</i> , 48(6):803-12 (1989).	
		GAGNON, et al., "A thermoplastic elastomer produced by the bacterium <i>Pseudomonas oleovorans</i> ", <i>Rubber World</i> , 207:32-38 (1992).	
		GAGNON, et al., "Chemical modification of bacterial elastomers: 1. Peroxide crosslinking", <i>Polymer</i> , 35:4358-67 (1994).	
		GAGNON, et al., "Chemical modification of bacterial elastomers: 2. Sulfur vulcanization", <i>Polymer</i> , 35:4368-75 (1994).	
		GERNGROSS and MARTIN, "Enzyme-catalyzed synthesis of poly[(R)-(-)-3-hydroxybutyrate]: formation of macroscopic granules in vitro", <i>Proc. Natl. Acad. Sci. USA</i> , 92:6279-83 (1995).	
		GERRA, et al., "Flumazenil effects on growth hormone response to gamma-hydroxybutyric acid", <i>International Clinical Psychopharmacology</i> , 9:211-215 (1994).	
		GÜRSEL, et al., "In vivo application of biodegradable controlled antibiotic release systems for the treatment of implant-related osteomyelitis", <i>Biomaterials</i> 22: 73-80 (2001).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>			
				Application Number		10/568,649	
				Filing Date		February 16, 2006	
				First Named Inventor		Georgio Terenghi	
				Group Art Unit		Not Yet Assigned	
				Examiner Name		Not Yet Assigned	
Sheet	15	of	26	Attorney Docket Number		TEPH 109	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		HADLOCK, et al., "Ocular cell monolayers cultured on biodegradable substrates", <i>Tissue Eng.</i> , 5(3):187-96 (1999).	
		HAZARI, et al., "A new resorbable wrap-around implant as an alternative nerve repair technique", <i>J. Hand Surgery</i> , 24(3): 291-295 (1999).	
		HAZARI, et al., "A resorbable nerve conduit as an alternative to nerve autograft in nerve gap repair", <i>Br J Plast Surg.</i> , 52(8):653-7 (1999).	
		HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of <i>Escherichia coli</i> ", <i>FEMS Microbiol. Lett.</i> , 153:411-18 (1997).	
		HEYDORN, et al., "A new look at pericardial substitutes", <i>J. Thorac. Cardiovasc. Surg.</i> , 94:291-96 (1987).	
		HOCKING & MARCHESSAULT, "Biopolyesters" in <u>Chemistry and Technology of Biodegradable Polymers</u> , (G.J.L. Griffin, ed.), pp. 48-96, Chapman and Hall: London, 1994.	
		HOCKING & MARCHESSAULT, "Syndiotactic poly[(R,S)-β-hydroxybutyrate] isolated from methyaluminoxane-catalyzed polymerization", <i>Polym. Bull.</i> , 30:163-70 (1993).	
		HOLMES, "Biologically Produced (R)-3-hydroxyalkanoate Polymers and Copolymers", in <u>Developments in Crystalline Polymers</u> (Bassett, ed.), pp. 1-65, Elsevier: London, 1988.	
		HOLMES, et al., "Applications of PHB—a microbially produced biodegradable thermoplastic", <i>Phys Technol.</i> , 16:32-36 (1985).	
		HORI, et al., "Chemical synthesis of high molecular weight poly(3-hydroxybutyrate-co-4-hydroxybutyrate)", <i>Polymer</i> , 36:4703-05 (1996).	
		HORI, et al., "Ring-Opening Copolymerization of Optically Active β-Butyrolactone with Several Lactones Catalyzed by Distannoxane Complexes: Synthesis of New Biodegradable Polyesters", <i>Macromolecules</i> , 26:4388-90 (1993).	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number		10/568,649
				Filing Date		February 16, 2006
				First Named Inventor		Georgio Terenghi
				Group Art Unit		Not Yet Assigned
				Examiner Name		Not Yet Assigned
Sheet	16	of	26	Attorney Docket Number		TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		HORI, et al., "Ring-Opening Polymerization of Optically Active β-Butyrolactone Using Distannoxane Catalysts: Synthesis of High Molecular Weight Poly(3-hydroxybutyrate)", <i>Macromolecules</i> , 26:5533-34 (1993).	
		HOROWITZ, et al., "Novel Thermal Route to an Amorphous, Film-Forming Polymer Latex", <i>Macromolecules</i> , 32:3347-3352 (1999).	
		HORSCH, "Inheritance of Functional Foreign Genes in Plants" <i>Science</i> , 223: 496-498 (1984).	
		HUIJBERTS, et al., "Pseudomonas putida KT2442 cultivated on glucose accumulates poly(3-hydroxyalkanoates) consisting of saturated and unsaturated monomers", <i>Appl Environ Microbiol.</i> , 58(2):536-44 (1992).	
		HUTMACHER, et al., "A review of material properties of biodegradable and bioresorbable polymers and devices for GTR and GBR applications", <i>Int. J. Oral Maxillofac. Implants</i> , 11(5):667-78 (1996).	
		KAMEYAMA, et al., "Novel sequence-ordered polymers by transformation of polymer backbone: Quantitative and regioselective insertion of Thiranes into poly( S-aryl thioester)", <i>Macromol.</i> , 32:1407-1412 (1999).	
		KASSAB, et al., "Embolization with polyhydroxybutyrate (PHB) microspheres: In vivo studies", <i>J. Bioact. Compat. Polym.</i> , 14:291-303 (1999).	
		KAUFMAN and NELSON, "An overview of gamma-hydroxybutyrate catabolism: the role of the cytosolic NADP(+) -dependent oxidoreductase EC 1.1.1.19 and of a mitochondrial hydroxyacid-oxoacid transhydrogenase in the initial, rate-limiting step in this pathway", <i>Neurochemical Research</i> , 16:965-974 (1991).	
		KEELER, "Don't Let Food Go To Waste- Make Plastic Out of It", <i>R&amp;D Magazine</i> , pp. 52-57 (1991).	
		KEELER, "Plastics Grown in Bacteria Inch Toward the Market", <i>R&amp;D Magazine</i> , pp. 46-52 (1991).	
		KEMNITZER, et al., "Preparation of predominantly Syndiotactic Poly(β-hydroxybutyrate) by the Tributyltin Methoxide Catalyzed Ring-Opening Polymerization of racemic β-Butyrolactone", <i>Macromolecules</i> , 26:1221-29 (1993).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number		10/568,649
				Filing Date		February 16, 2006
				First Named Inventor		Georgio Terenghi
				Group Art Unit		Not Yet Assigned
				Examiner Name		Not Yet Assigned
Sheet	17	of	26	Attorney Docket Number		TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		KIM and MOONEY, "Engineering smooth muscle tissue with a predefined structure", <i>J. Biomed. Mat. Res.</i> , 41(2):322-332 (1998).	
		KISHIDA, et al., "Formulation-assisted biodegradable polymer matrices", <i>Chemical and Pharmaceutical Bulletin</i> , 37:1954-56 (1989).	
		KLEINSCHMIDT, et al., "Continuous sedation during spinal anaesthesia: gamma-hydroxybutyrate vs. propofol", <i>European Journal of Anaesthesiology</i> , 16:23-30 (1999).	
		KLEINSCHMIDT, et al., "Total intravenous anaesthesia using propofol, gamma-hydroxybutyrate or midazolam in combination with sufentanil for patients undergoing coronary artery bypass surgery", <i>European Journal of Anaesthesiology</i> , 14:590-599 (1997).	
		KLINGE, et al., "Functional assessment and tissue response of short- and long-term absorbable surgical meshes", <i>Biomaterials</i> , 22:1415-1424 (2001).	
		KOOSHA, "Preparation and characterization of biodegradable polymeric drug carriers", Ph.D. Dissertation, 1989, Univ. Nottingham, UK., <i>Diss. Abstr. Int.</i> , B 51:1206 (1990).	
		KOOSHA, et al., "Polyhydroxybutyrate as a drug carrier", <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 6(2):117-30 (1989).	
		KORKUSUZ, et al., <i>In vivo</i> response to biodegradable controlled antibiotic release systems, <i>J. Biomed. Mater. Res.</i> 55: 217-228 (2001).	
		KORSATKO, et al., "The influence of the molecular weight of poly-D(-)-3-hydroxybutyric acid on its use as a retard matrix for sustained drug release", <i>8th Europ. Congress of Biopharmaceutics and Pharmacokinetics</i> , 1:234-242 (1987).	
		KORTE and GELT, "Hochdruckreaktionen. II. Die Polymerisation Von $\gamma$ butyrolacton und $\gamma$ -valerolactam bei hohen drücken", <i>Polymer Lett.</i> , 4:685-89 (1966).	
		KUSAKA, et al., "Microbial synthesis and Physical Properties of ultra-high-molecular-weight poly[(R)-3-hydroxybutyrate]", <i>Pure Appl. Chem.</i> , A35:319-35 (1998).	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	18	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		LAFFERTY, et al., "Microbial Production of Poly-b-hydroxybutyric acid" in <u>Biotechnology</u> (H.J. Rehm and G. Reed, eds.), Verlagsgesellschaft, Weinheim, vol. 66, pp. 135-76 (1988).	
		LAMBA, et al., "Degradation of polyurethanes", in <u>Polyurethanes in Biomedical Applications</u> (CRC Press:Boca Raton, Florida, 1998).	
		LANZA, et al., <u>Principles of Tissue Engineering</u> (Academic Press:Austin, 1997).	
		LE BORGNE and SPASSKY, "Stereoelective polymerization of β-butyrolactone", <i>Polymer</i> , 30:2312-19 (1989).	
		LEBEDEV and YEVSTROPOV, "Thermoplastic properties of polylactones", <i>Makromol. Chem.</i> , 185:1235-1253 (1984).	
		LEE, et al., "Copolymerization of γ-butyrolactone and β-butyrolactone", <i>Macromol. Chem. Phys.</i> , 198:1109-20 (1997).	
		LEMOIGNE and ROUKHELMAN, "Fermentation β-Hydroxybutyrique Caracterisation et Evolution Des Produits de Deshydratation et de Polymerisation de L'acide β-Dehydroxybutyrique", <i>Annales des fermentations</i> , 5:527-36 (1925).	
		LJUNGBERG, et al. "Neuronal survival using a resorbable synthetic conduit as an alternative to primary nerve repair", <i>Microsurgery</i> , 19(6):259-264 (1999).	
		LLOYD, et al., "Transformation of <i>Arabidopsis thaliana</i> with <i>Agrobacterium tumefaciens</i> ", <i>Science</i> , 234: 464-66 (1986).	
		LÜTKE-EVERSLÖH et al., "Identification of a new class of biopolymer: Bacterial synthesis of a sulfur-containing polymer with thioester linkages", <i>Microbiology</i> , 147(1): 11-19 (2001).	
		LÜTKE-EVERSLÖH et al., "List of submitted abstracts", <i>The 8<sup>th</sup> International Symposium on Biological Polyesters</i> , (2000).	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/568,649
		Filing Date	February 16, 2006
		First Named Inventor	Georgio Terenghi
		Group Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
Sheet 19 of 26	Attorney Docket Number	TEPH 109	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		MADISON and HUISMAN, "Metabolic engineering of poly(3-hydroxyalkanoates): from DNA to plastic", <i>Microbiol. Molec. Biol. Rev.</i> , 63:21-53 (1999).	
		MALM, et al., "A new biodegradable patch for closure of atrial septal defect. An experimental study", <i>Scand. J. Thorac. Cardiovasc. Surg.</i> , 26(1):9-14 (1992).	
		MALM, et al., "Enlargement of the right ventricular outflow tract and the pulmonary artery with a new biodegradable patch in transannular position", <i>Eur. Surg. Res.</i> , 26(5):298-308 (1994).	
		MALM, et al., "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches. An experimental study", <i>J. Thorac. Cardiovasc. Surg.</i> , 104(3):600-07 (1992).	
		MARTIN and WILLIAMS, "Medical application of poly-4-hydroxybutyrate: A strong flexible absorbable biomaterial", <i>Biochem. Eng. J.</i> , 16:97-105 (2003).	
		MATHIOWITZ AND LANGER, "Polyanhydride microspheres as drug delivery systems" in <i>Microcapsules Nanopart. Med. Pharm.</i> (Donbrow, ed.), pp. 99-123 (CRC:Boca Raton, Florida, 1992).	
		MAYSINGER, "Microencapsulation and the Grafting of Genetically Transformed Cells as Therapeutic Strategies to rescue Degenerating Neurons of the CNS", <i>Reviews in the Neurosciences</i> , 6:15-33 (1995).	
		MCMILLIN, "Elastomers for Biomedical Applications", <i>Rubber Chem. Technol.</i> , 67:417-46 (1994).	
		MCWILLIAMS, "Plastics as High as an Elephant's Eye?" <i>Business Week</i> , pp. 110-11 (1991).	
		MODELLI, et al., "Kinetics of aerobic polymer degradation in soil by means of the ASTM D 5988-96 standard method", <i>J Environ Polym Degr.</i> , 7:109-116 (1999).	
		MÜH, et al., "PHA synthase from chromatium vinosum: cysteine 149 is involved in covalent catalysis", <i>Bioche.</i> , 38:826-837 (1999).	

Examiner's Signature	Date Considered
----------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	20	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		MÜLLER, et al., "Poly(hydroxyalkanoates): A Fifth Class of Physiologically Important Organic Biopolymers", <i>Angew. Chem. Int. Ed. Engl.</i> , 32: 477-502 (1993).	
		NAKAMURA et al., "Biosynthesis and characteristics of bacterial poly(3-hydroxybutyrate-co-3-hydroxypropionate)", <i>Macromol. Rep.</i> , A28, 15-24 (1991).	
		NAKAMURA, et al., "Microbial synthesis and characterization of poly(3-hydroxybutyrate-co-4-hydroxybutyrate)", <i>Macromol.</i> , 25:4237-4241 (1992).	
		NELSON, et al., "The extraneural distribution of gamma-hydroxybutyrate", <i>J. Neurochem.</i> , 37:1345-1348 (1981).	
		NIKLASON, et al., "Functional arteries grown in vitro", <i>Science</i> , 284(5413):489-93 (1999).	
		NOBES, et al., "Polyhydroxyalkanoates: Materials for delivery systems", <i>Drug Del.</i> , 5:167-77 (1998).	
		OGAWA, et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Poly Lactic Acid or Copoly(Lactic/Glycolic) Acid", <i>Chem. Pharm. Bull.</i> , 36:1095-103 (1988).	
		OTERA, et al., "Distannoxane as reverse micelle-type catalyst: novel solvent effect on reaction rate of transesterification", <i>J. Org. Chem.</i> , 54:4013-14 (1989).	
		OTERA, et al., "Distannoxane-catalysed transesterification of 1,n-Dioldiacetates. Selective transformation of either of chemically equivalent functional groups", <i>J. Chem. Soc. Chem. Commun.</i> , 1742-43 (1991).	
		OTERA, et al., "Novel distannoxane-catalyzed transesterification and a new entry to $\alpha,\beta$ -unsaturated carboxylic acids", <i>Tetrahedron Lett.</i> , 27:2383-86 (1986).	
		OTERA, et al., "Novel template effects of distannoxane catalysts in highly efficient transesterification and esterification", <i>J. Org. Chem.</i> , 56:5307-11 (1991).	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/568,649	
			Filing Date	February 16, 2006	
			First Named Inventor	Georgio Terenghi	
			Group Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
Sheet	21	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		PEDRÓS-ALIO <i>et al.</i> , "The influence of poly-D-hydroxybutyrate accumulation on cell volume and buoyant density in <i>Alcaligenes eutrophus</i> ", <i>Arch. Microbiol.</i> 143:178-184 (1985).	
		PEOPLES, et al., "Poly-β-hydroxybutyrate Biosynthesis in <i>Alcaligenes eutrophus</i> H16", <i>J. Biol. Chem.</i> 264(26):15293-97 (1989).	
		PEOPLES, et al., "Polyhydroxybutyrate (PHB): A Model System for Biopolymer Engineering: II", in <i>Novel Biodegradable Microbial Polymers</i> (Dawes, ed.) pp. 191-202, Kluwer Academic Publishers: Netherlands (1990).	
		PERRIN & ENGLISH, "Polycaprolactone", in <i>Handbook of Biodegradable Polymers</i> (Domb, et al., eds.) pp. 63-77 (Harwood, Amsterdam, 1997).	
		PINTO, "Hydrogen Peroxide as depyrogenation agent for medical devices components", <i>Revista De Saude Publica</i> , 29(1):75-79 (1995).	
		POIRIER, "Perspectives on the production of polyhydroxyalkanoates in plants", <i>FEMS Microbiology Reviews</i> , 103:237-46 (1992).	
		POIRIER, et al., "Progress Toward Biologically Produced Biodegradable thermoplastics", <i>Adv. Mater.</i> , 5(1):30-37 (1993).	
		POOL, "In Search of the Plastic Potato", <i>Science</i> , 245: 1187-89 (1989).	
		POUTON and AKHTAR, "Biosynthetic polyhydroxyalkanoates and their potential in drug delivery", <i>Adv. Drug Delivery Rev.</i> , 18:133-62 (1996).	
		REHM and STEINBÜCHEL, "Biochemical and genetic analysis of PHA synthases and other proteins required for PHA synthesis", <i>Int. J. Biol. Macromol.</i> 25:3-19 (1999).	
		RENSTAD, et al., "The influence of processing induced differences in molecular structure on the biological and non-biological degradation of poly (3-hydroxybutyrate-co-3-hydroxyvalerate), P(3-HB-co-3-HV)", <i>Polymer Degradation and Stability</i> , 63:201-211 (1999).	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	22	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		REYNOLDS, <u>Martindale: The Extra Pharmacopeia</u> , p. 1264, (Thirty First Edition, Royal Pharmaceutical Society, London, 1997).	
		RIVARD, et al., "Fibroblast seeding and culture in biodegradable porous substrates", <i>J. Appl. Biomater.</i> , 6(1):65-68 (1995).	
		ROPERO-MILLER & GOLDBERGER, "Recreational drugs. Current trends in the 90s", <i>Clinics in Laboratory Medicine</i> , 18:727-746 (1998).	
		SABBAGH, et al., "3-Mercaptopropionic acid, a potent inhibitor of fatty acid oxidation in rat heart mitochondria", <i>J. Biol. Chem.</i> 260:7337-7342 (1985).	
		SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in <i>Comamonas acidovorans</i> ", <i>Int. J. Biol. Macromol.</i> , 16(2):99-104 (1994).	
		SCHARF, et al., "Pharmacokinetics of gammahydroxybutyrate (GHB) in narcoleptic patients", <i>Sleep</i> 21:507-514 (1998).	
		SCHLEGEL, et al., "Ein submersverfahren zur kultur wasserstoffoxydierender bakterien: Wachstumsphysiologische untersuchungen", <i>Arch. Mikrobiol.</i> 38:209-222 (1961).	
		SCHWARTZ and GOODMAN, <u>Plastic Materials and Processes</u> , (Van Nostrand Reinhold Company:New York, 1982).	
		SENDELBECK & GIRDIS, "Disposition of a 14C-labeled bioerodible polyorthoester and its hydrolysis products, 4-hydroxybutyrate and cis,trans-1,4-bis(hydroxymethyl)cyclohexane, in rats", <i>Drug Metabolism &amp; Disposition</i> 13:291-295 (1985).	
		SHINOKA & MAYER, "New frontiers in tissue engineering: tissue engineered heart valves" in <u>Synthetic Bioabsorbable Polymer Scaffolds</u> (Atala & Mooney, eds.) pp. 187-198 Birkhäuser Boston, 1997.	
		SHINOKA, et al., "Creation of viable pulmonary artery autografts through tissue engineering", <i>J. Thorac. Cardiovasc. Surg.</i> , 115(3):536-46 (1998).	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number		10/568,649
				Filing Date		February 16, 2006
				First Named Inventor		Georgio Terenghi
				Group Art Unit		Not Yet Assigned
				Examiner Name		Not Yet Assigned
Sheet	23	of	26	Attorney Docket Number		TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		SHINOKA, et al., "Tissue engineering heart valves: valve leaflet replacement study in a lamb model" <i>Ann. Thorac. Surg.</i> , 60(Suppl 3):S513-16 (1995).	
		SIM, et al., "PHA synthase activity controls the molecular weight and polydispersity of polyhydroxybutyrate <i>in vivo</i> ", <i>Nat. Biotechnol.</i> , 15(1):63-67 (1997).	
		SKREDE et al, "Thia fatty acids, metabolism and metabolic effects" in <i>Biochim Biophys Acta</i> 1344:115-31 (1997).	
		SNEAD, "The gamma-hydroxybutyrate model of absence seizures: correlation of regional brain levels of gamma-hydroxybutyric acid and gamma-butyrolactone with spike wave discharges", <i>Neuropharmacology</i> 30:161-167 (1991).	
		SONG, et al., "Production of poly(4-hydroxybutyric acid) by fed-batch cultures of recombinant strains of <i>Escherichia coli</i> ", <i>Biotechnol. Lett.</i> 21:193-197 (1999).	
		SPEER and WARREN, "Arthroscopic shoulder stabilization. A role for biodegradable materials", <i>Clin. Orthop.</i> , (291):67-74 (1993).	
		STANTON and GAGNÉ, "The remarkable catalytic activity of alkali-metal alkoxide clusters in the ester interchange reaction", <i>J. Am. Chem. Soc.</i> , 119:5075-76 (1997).	
		STEINBÜCHEL and VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids", <i>FEMS Microbiol. Lett.</i> , 128:219-28 (1995).	
		STEINBÜCHEL and WIESE, "A <i>Pseudomonas</i> strain accumulating polyesters of 3-hydroxybutyric acid and medium-chain-length 3-hydroxyalkanoic acids", <i>Appl. Microbiol. Biotechnol.</i> , 37:691-97 (1992).	
		STEINBÜCHEL, "Polyhydroxyalkanoic Acids" in <i>Biomaterials</i> (Byrom, ed.), pp. 125-213 (MacMillan Publishers:London 1991).	
		STEINBÜCHEL, et al., "Molecular basis for biosynthesis and accumulation of polyhydroxyalkanoic acids in bacteria", <i>FEMS Microbiology Reviews</i> , 103: 217-30 (1992).	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete If Known</b>			
			Application Number		10/568,649	
			Filing Date		February 16, 2006	
			First Named Inventor		Georgio Terenghi	
			Group Art Unit		Not Yet Assigned	
			Examiner Name		Not Yet Assigned	
Sheet	24	of	26	Attorney Docket Number		TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		TAKAGI et al., "Biosynthesis of polyhydroxyalkanoate with a thiophenoxy side group obtained from <i>Pseudomonas putida</i> ", <i>Macromolecules</i> , 32: 8315-8318 (1999).	
		TALJA, et al., "Bioabsorbable and biodegradable stents in urology", <i>J. Endourol.</i> , 11(6):391-97 (1997).	
		TANAHASHI and DOI, "Thermal Properties and Stereoregularity of Poly(3-hydroxybutyrate) Prepared from optically Active $\beta$ -Butyrolactone with a Zinc-Based Catalyst", <i>Macromolecules</i> , 24:5732-33 (1991).	
		TANAKA, et al., "Clinical application of 4-hydroxybutyrate sodium and 4-butyrolactone in neuropsychiatric patients", <i>Folia Psychiatrica et Neurologica</i> 20:9-17 (1966).	
		TANGUAY, et al., "Current status of biodegradable stents", <i>Cardiol. Clin.</i> , 12(4):699-713 (1994).	
		Tepha announces submission of device master file to FDA (June 3, 2002). Retrieved 12-17-2004, from <a href="http://www.pressrelease.be/script_UK/newsdetail.asp?ndays=m&amp;ID=695">http://www.pressrelease.be/script_UK/newsdetail.asp?ndays=m&amp;ID=695</a>	
		Tepha submits device master file to FDA- New Technology (July 2, 2002). Retrieved on 12-17-2004, from <a href="http://www.findarticles.com/p/articles/mi_mOPC/is_7_26/ai_89018276">http://www.findarticles.com/p/articles/mi_mOPC/is_7_26/ai_89018276</a>	
		TSURUTA, et al., <i>Biomedical Applications of Polymeric Materials</i> (CRC Press, Boca Raton, Florida, 1993).	
		TUNNICLIFF, "Sites of action of gamma-hydroxybutyrate (GHB)--a neuroactive drug with abuse potential", <i>Clinical Toxicology</i> , 35:581-590 (1997).	
		TÜRESIN, et al., "Biodegradable polyhydroxyalkanoate implants for osteomyelitis therapy: <i>in vitro</i> antibiotic release," <i>J. Biomater. Sci. Polymer Edn.</i> 12: 195-207 (2001).	
		TURKE, "Absorbable Biomaterial is suited for diverse applications" (06-03-2002). Retrieved on 12-17-2004, from <a href="http://www.devicelink.com/mpmn/archive/01/10/009.html">http://www.devicelink.com/mpmn/archive/01/10/009.html</a>	

Examiner's Signature		Date Considered	
-------------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/568,649	
			Filing Date	February 16, 2006	
			First Named Inventor	Georgio Terenghi	
			Group Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
Sheet	25	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		UNVERDORBEN, et al., "Polyhydroxybutyrate (PHB) Biodegradable Stent-Experience in the Rabbit", <i>American J. Cardiol.</i> , TCT Abstracts/Oral, p.5S:TCT-11 (Oct. 1998).	
		VALENTIN, et al., "Identification of 4-hydroxyhexanoic acid as a new constituent of biosynthetic polyhydroxyalkanoic acids from bacteria", <i>Appl. Microbiol. Biotechnol.</i> , 40:710-16 (1994).	
		VALENTIN, et al., "Identification of 5-hydroxyhexanoic acid, 4-hydroxyheptanoic acid and 4-hydroxyoctanoic acid as new constituents of bacterial polyhydroxyalkanoic acids", <i>Appl. Microbiol. Biotechnol.</i> , 46:261-67 (1996).	
		VALENTIN, et al., "Production of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in recombinant <i>Escherichia coli</i> grown on glucose", <i>J. Biotechnol.</i> , 58:33-38 (1997).	
		VON SCHROEDER, et al., "The use of polylactic acid matrix and periosteal grafts for the reconstruction of rabbit knee articular defects", <i>J. Biomed. Mater. Res.</i> , 25(3):329-39 (1991).	
		WALLEN and ROHWEDDER, "Poly-β-hydroxyalkanoate from Activated Sludge", <i>Environ. Sci. Technol.</i> , 8:576-79 (1974).	
		WIDMER and MIKOS, "Fabrication of biodegradable polymer scaffolds for tissue engineering" in <i>Frontiers in Tissue Engineering</i> (Patrick, et al., Eds.) Ch. II.5, pp.107-20 (Elsevier Science, New York, 1998).	
		WILLIAMS and PEOPLES, "Biodegradable plastics from plants", <i>Chemtech</i> , 26:38-44 (1996).	
		WILLIAMS, et al., "Application of PHAs in Medicine and Pharmacy", <i>Polyesters III</i> , 4:91-127 (2002).	
		WILLIAMS, et al., "Making plastics green", <i>Chem. Br.</i> , 33:29-32 (1997).	
		WILLIAMS, et al., "PHA applications: addressing the price performance issue. I. Tissue engineering", <i>Int. J. Biol. Macromol.</i> , 25(1-3): 111-121 (1999).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	26	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		WODZINSKA, et al., "Polyhydroxybutyrate synthase: Evidence for covalent catalysis", <i>J. Am. Chem. Soc.</i> 118:6319-6320 (1996).	
		WONG and MOONEY, "Synthesis and properties of biodegradable polymers used as synthetic matrices for tissue engineering", in <i>Synthetic Bio degradable Polymer Scaffolds</i> (Atala, et al., eds.) pp. 51-82 (Birkhäuser: Boston, 1997).	
		WORSEY and WILLIAMS, "Metabolism of toluene and xylenes by <i>Pseudomonas putida</i> (arvilla) mt-2: evidence for a new function of the TOL plasmid" <i>J Bacteriol</i> 124:7-13 (1975).	
		XIE, et al., "Ring-opening Polymerization of $\beta$ -butyrolactone by Thermophilic Lipases", <i>Macromolecules</i> , 30:6997-98 (1997).	
		YAGMURLU, et al., "Sulbactam-cefoperazone polyhydroxybutyrate-co-hydroxyvalerate (PHBV) local antibiotic delivery system: in vivo effectiveness and biocompatibility in the treatment of implant-related experimental osteomyelitis", <i>J Biomed Mater Res.</i> , 46(4):494-503 (1999).	
		YAMADA, et al., "Development of a dural substitute from synthetic bioabsorbable polymers", <i>J. Neurosurg.</i> , 86(6):1012-17 (1997).	
		ZUND, et al., "The in vitro construction of a tissue engineered bioprosthetic heart valve", <i>Eur. J. Cardiothorac. Surg.</i> , 11(3):493-97 (1997).	

Examiner's Signature	Date Considered
-------------------------	--------------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.